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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,788	01/10/2001	Keith Anderson	6116.200-US	8259

7590 03/13/2007

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EXAMINER	
TELLER, ROY R	
ART UNIT	PAPER NUMBER
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/757,788	ANDERSON ET AL.	
	Examiner	Art Unit	
	Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-8,15,16,18,19,21-23 and 25-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-8,15,16,18,19,21-23 and 25-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/21/06 has been entered.

Claims 1-3, 5-8, 15-16, 18-19, 21-23 and 25-27 are to be examined.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 48, 49 and 54 of copending

Application No.09/772,607 . Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention is drawn to a formulation comprising a GLP-1 compound having attached thereto a lipophilic substituent comprising 14-18 carbon atoms, where said attachment of said lipophilic subsituent to said GLP-1 compounds is optionally via a spacer and wherein said formulation upon nebulization achieves a mass median aerodynamic diameter of less than 10 um . Claim 48 of the '607 application is a derivative of GLP-1 or an analog thereof wherein a lipophilic substituent having 8 to 40 carbon atoms and optionally having an amino group is optionally via a spacer attached to the C-terminal amino acid of GLP-1 . Claim 49 of the '607 application is a derivative of claim 48, wherein the lipophilic substituent has 12 to 35 carbon atoms. Claim 54 recites a lipophilic substituent between 10 to 16. Page 6 of the '607 specification describes a composition which may be a powder or a liquid for the administration of the peptide derivative according to the present invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 2, 3, 5, 6, 7, 8, 15, 16, 18 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Knudsen et al. (USPN 6,268,343)

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The instant invention is drawn to a formulation comprising a GLP-1 compound having attached thereto a lipophilic substituent comprising 14-18 carbon atoms, where said attachment of said lipophilic subsituent to said GLP-1 compounds is optionally via a spacer and wherein said formulation upon nebulization achieves a mass median aerodynamic diameter of less than 10 um.

Knudsen et al discloses a GLP-1 derivative having a lipophilic substituent of 14, 16 and 18 carbons, see, i.e., for example column 267, lines 23-28. This reads on the limitations of instant claim 1. Knudsen discloses GLP-1 and exendin 9-39, see, i.e, for example, column 2, lines 61-64. This reads on the limitations of instant claims 2 and 3. Knudsen discloses a GLP-1 derivative wherein the lipophilic substituent is hexadecanoyl, see, i.e., for example, claim 13. This reads on the limitations of instant claim 5. Knudesen discloses a spacer for use in the GLP-1 derivative, see, i.e, for example, claim 1. This reads on the limitations of instant claims 6 and 7. Knudsen discloses the GLP-1 derivative, which is Lys26 (N -epsilon alpha –glutamyl)(N alpha decanoyl))),Arg34-GLP-1 (7-37), see, i.e, for example, claim 26. This reads on the limitations of

instant claim 8. Knudsen discloses a composition comprising an isotonic agent, preservative and buffer, see, i.e., for example, claim 29. This reads on the limitations of instant claim 15. Knudsen discloses a GLP-1 suitable for administration by injectable solution, which contains not less than about 2 mg/ml and not more than about 100 mg/ml of GLP-1, see, i.e, for example column 169, lines 38-48. This reads on the limitations of instant claim 16. Knudsen discloses that the GLP peptides can be administered in the form of nasal and pulmonary sprays, see, i.e, column 170, lines 23-35. Since the reference discloses liquid administration that can be formulated into a spray and since Knudsen discloses the formulation with the same peptide, a formulation comprising a GLP-1 compound having attached thereto a lipophilic substituent comprising 14-18 carbon atoms, where said attachment of said lipophilic subsituent to said GLP-1 compounds is optionally via a spacer, the formulation would inherently possess the ability to have the claimed diameter "upon nebulization". This would read on the limitations of instant claims 1, 18 and 19.

Therefore, the reference is deemed to anticipate the instant claims.

Claims 21-23 and 25-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Hughes et al. (6,720,407).

The instant invention is drawn to a dry formulation comprising a GLP-1 compound having attached thereto a lipophilic substituent comprising 14-18 carbon atoms, where said attachment of said lipophilic subsituent to said GLP-1 compounds is optionally via a spacer and wherein said formulation upon nebulization achieves a mass median aerodynamic diameter of less than 10 um.

Hughes et al. discloses GLP-1 in the form of a dry powder, wherein the dry powder has a particle size about 10 microns mass median aerodynamic diameter and wherein the dry powder has a particle size of about 1 to about 5 microns mass median aerodynamic diameter, see, i.e., for example, column 4, line 37- column 5, line 26, claims 5, 6, 7 and 8. This reads on instant claims 25 and 26. Hughes et al. discloses formulations of GLP-1 for administration from a dry powder typically include a finely divided dry powder containing peptide, see, column 8, lines 53-55. This reads on instant claims 21-23. Hughes discloses GLP-1 and GLP-1 analogs and derivatives for administration from dry powder containing the peptide, the powder can also contain another additive or the like, see, i.e, column 8, lines 53-55, 57. The instant specification describes the term lipophilic substituent as comprising 4-40 carbon atoms. Hughes discloses SEQ ID NO:3, in which R2 is C6-C10 unbrached acyl. See column 6, lines 6-15. This would read on instant claim 27.

Therefore, the cited reference is deemed to anticipate the instant claims.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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3/2/07
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3/5/07
ANISH GUPTA
PRIMARY EXAMINER